## **Footnotes**

- 1. "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (July 10, 2003). [http://www.cfsan.fda.gov/~dms/nuttf-e.html]
- 2. See guidance entitled "Interim Evidence-based Ranking System for Scientific Data," July 10, 2003. [http://www.cfsan.fda.gov/~dms/hclmgui4.html]
- 3. In an intervention study, subjects similar to each other are randomly assigned to either receive the intervention or not to receive the intervention, whereas in an observational study, the subjects (or their medical records) are observed for a certain outcome (i.e., disease). Intervention studies provide the strongest evidence for an effect. See Guidance entitled "Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" (December 22, 1999). [http://www.cfsan.fda.gov/~dms/ssaguide.html]
- 4. Replication of scientific findings is important for evaluating the strength of scientific evidence (An Introduction to Scientific Research, E. Bright Wilson Jr., pages 46-48, Dover Publications, 1990) and Ioannidis JPA. Contradicted and initially stronger effects in highly cited clinical research. JAMA, 294: 218-228, 2005.
- 5. Consistency of findings among similar and different study designs is important for evaluating causation and the strength of scientific evidence (Hill A.B. The environment and disease: association or causation? Proc R Soc Med 1965;58:295-300); See also Systems to rate the scientific evidence, Agency for Healthcare Research and Quality <a href="http://www.ahrq.gov/clinic/epcsums/strengthsum.htm#Contents">http://www.ahrq.gov/clinic/epcsums/strengthsum.htm#Contents</a>, defining "consistency" as "the extent to which similar findings are reported using similar and different study designs."
- 6. Kidney Stones in Adults, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, U.S. Department of Health and Human Services <a href="http://kidney.niddk.nih.gov/kudiseases/pubs/stonesadults/index.htm">http://kidney.niddk.nih.gov/kudiseases/pubs/stonesadults/index.htm</a>